DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2350
Boston, MA 02203

Northeast Division of Survey & Certification

CENTERS FOR MEDICARE & MEDICAID SERVICES

IMPORTANT NOTICE – ACTION NECESSARY

October 19, 2018 Via certified mail

Alexander Finkelstein, M.D.
Laboratory Director
Bridgeport Hospital Laboratory
267 Grant Street
Bridgeport, CT 06610 CLIA number: 07D0099572

RE: PROPOSED SANCTIONS – CONDITIONS NOT MET

Dear Finkelstein:

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, and bill for services provided to Medicare beneficiaries or Medicaid recipients under Titles XVIII and XIX of the Social Security Act, it must comply with all CLIA Requirements (42 C.F.R. § 493). The American Society for Cytotechnology (ASCT) functions as an agent of the Centers for Medicare & Medicaid Services (CMS), and has the authority to inspect a laboratory and its records under the CLIA Public Law 100-578.

Federal regulations require onsite surveys to determine whether or not a laboratory is in compliance with the applicable CLIA regulations in section 353 of the Public Health Service Act (42 U.S.C. § 263a) and 42 C.F.R. § 493.

The ASCT conducted a complaint survey at Bridgeport Hospital Laboratory, and found condition-level deficiencies. The CMS Boston Regional Office (RO) requested an acceptable allegation of compliance (AOC) and creditable evidence of correction. The laboratory failed to submit an acceptable AOC. The CMS RO notified your laboratory by its letter dated August 8, 2018, that it would take sanction actions against the Bridgeport Hospital Laboratory's CLIA certificate if it failed to demonstrate compliance.

Proposed Sanctions

Accordingly, pursuant to 42 C.F.R. §§ 493.1806 and 493.1840(a)(3), based on the laboratory's failure to meet all CLIA Conditions, and based on the failure by the owner(s) and director of the laboratory to comply with the certificate requirements and performance standards as evidenced by the deficiencies cited at the July 20, 2018 survey, we are taking action to impose the following sanctions against the Bridgeport Hospital Laboratory's CLIA certificate:

o 42 U.S.C. § 263a(i)(3), 42 C.F.R. §§ 493.1806, 493.1840(a)(3) and 493.1840(e) – Principal Sanction: **Revocation** of the laboratory's CLIA certificate effective December 19, 2018. If imposed, the laboratory has 60 days to appeal the determination to revoke the laboratory's CLIA certificate. If a timely hearing request is received, revocation of the laboratory's CLIA certificate will become effective following the administrative hearing decision, if our determination of non-compliance is upheld.

o 42 C.F.R. §§ 493.1806(c)(3), 493.1810(c)(2)(ii), 493.1810(d) and 493.1834 – Alternative Sanction: **Civil Money Penalty** in the amount of $3,000 per day for each day of non-compliance effective November 5, 2018. If the laboratory requests a hearing, the civil money penalty amount will not be collected until after the hearing decision is rendered. However, if imposed, the $3,000/ day will begin to accrue on November 5, 2018, and will continue to accrue until it can be verified that the laboratory is in compliance with all Condition-level requirements or the laboratory's CLIA certificate is revoked.

In determining the amount of the penalty, CMS has taken into account the following factors: (1) the laboratory was found to be out of compliance with four CLIA Condition-level requirements as well as numerous standard-level CLIA requirements at the survey completed on July 20, 2018; (2) the laboratory has failed to correct the deficiencies after being provided an opportunity to do so; (3) the laboratory director failed to establish and maintain quality control and quality assessment programs to assure the accuracy of patient test results; and (4) the laboratory has expressed no rational reason for its failure to achieve compliance with all applicable Condition-level CLIA requirements.

o 42 C.F.R. §§ 493.1806(c)(1), 493.1832, 493.1844(d)(1) and 493.1844(g)(1) – Alternative Sanction: **Directed Portion of a Plan of Correction** effective November 5, 2018. If imposed, the laboratory will be directed to submit to this office within ten calendar days from the date of the imposition notice a list of the names and addresses of all physicians and other clients who have used some or all of the laboratory's services since August 1, 2018. This list may be used to advise the laboratory's clients of the nature of its non-compliance and the nature and effective date of any sanctions imposed against the laboratory.

o 42 C.F.R. §§ 493.1807(a), 493.1808(a), 493.1842 and 493.1844(d)(3) – Principal Sanction: **Cancellation of the laboratory's approval to receive Medicare payments** for any laboratory services performed on or after November 5, 2018. If imposed, this sanction will be effectuated even if the laboratory files a timely appeal.

Moreover, in accordance with Section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c), if the sanction of cancellation of the laboratory's approval to receive Medicare payments is imposed, payment under the Medicaid program, Title XIX of the Social Security Act, will no longer be available to the laboratory for any laboratory services performed on or after November 5, 2018. *See* 42 C.F.R. § 440.2(b).

The laboratory is advised that the above sanctions cannot be avoided by the closure, discontinuation of testing, voluntary withdrawal from the CLIA program, or changes in certificate to a lower level of testing.

Appeal Rights

If, after imposition of these sanctions, Bridgeport Hospital Laboratory believes this determination to impose these actions against its CLIA certificate is not correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board in accordance with 42 C.F.R. § 493.1844(a)(1)-(2) and 42 C.F.R. §§ 498.40 through 498.78. A request for hearing must be filed **electronically** no later than **sixty (60) calendar days** after the date this letter is received (see 42 C.F.R. § 493.1844(f)). You should file your request for an appeal (accompanied by a copy of this letter) to the Department Appeals Board Electronic Filing System website (DAB E-file) at https:/ / dab.efile.hhs.gov. Please note: all documents must be submitted in Portable Document Format ("pdf:"). You are **required** to e-file your appeal request unless you do not have access to a computer or internet service. In such circumstances, you may file in writing, but must provide an explanation as to why you cannot file submissions electronically and request a waiver from e-filing in the mailed copy of your request for a hearing. Written request for appeals must also be filed no later than sixty (60) calendar days after the date this letter is received, and must be submitted to the following address:

Department of Health and Human Services
Departmental Appeals Board, MS 6132
Civil Remedies Division
330 Independence Ave, SW
Cohen Building, Room G-644
Washington, D.C. 20201

A copy of the hearing request should be sent to:

Daniel M. Kristola
Acting Branch Manager
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room-2350
Boston, MA 02203

The request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/ or findings and conclusions are incorrect. Evidence and arguments may also be presented at the hearing, where counsel may represent the laboratory at its own expense. **If a hearing is conducted and CMS' determination is upheld, the laboratory will be assessed a fee to cover the government's cost related to the hearing.** *See* 42 C.F.R. § 493.643(d)(2).

If the laboratory's CLIA certificate is revoked, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owner(s) or operator(s) (including director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. This prohibition applies to the owner(s) as well as the director at the time that the deficiencies were found which led to the current sanction actions.

If the sanctions become effective as referenced above, in accordance with 42 C.F.R. § 493.1850(a)(2), information regarding the actions against the laboratory's CLIA certificate will appear in the Laboratory Registry for the calendar year in which the actions are imposed. In addition, pursuant to 42 C.F.R. § 493.1844(g)(1), we will notify the general public by means of a notice published in a local newspaper, if the above sanctions are imposed.

You have ten days from the date of this notice, or until October 29, 2018, to submit in writing any evidence or information as to why the sanctions detailed above should not be imposed. If we do not receive a timely submission or if we determine that the submission is unpersuasive, we will notify you in writing that we will proceed to impose the above-referenced sanctions. We will provide you with the laboratory's appeal rights at that time.

Instructions for sending in Your Response

Your laboratory's response should be sent to:

Daniel M. Kristola
Branch Manager
Centers for Medicare & Medicaid Services
Certification and Enforcement Branch
JFK Federal Building, Room – 2350
Boston, MA 02203

A copy of any response the laboratory makes should also be sent to the State agency at the following address:

Connecticut Department of Public
P.O. Box 340308
410 Capitol Avenue, MS#12 FLIS
Hartford, CT 06134-0308

If you have questions regarding this letter, please contact Dina Caloggero at (617) 565-1286 or Bethzaida Rodriguez at (617) 565-2146.

Sincerely,

Daniel M. Kristola
Branch Manager
Certification and Enforcement Branch

Cc: Barbara Cass, Connecticut SA
Cheryl Wiseman, CMS Central Office

Dr. Finkelstein - via certified, return receipt # 91 7199 9991 7038 9231 3981